



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/012,269 02/01/93 KWON

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EXAMINER

MOSHER, M

ART UNIT

PAPER NUMBER

18N1/0821

BARNARD & BROWN
306 STATE STREET, #220
ITHACA, NEW YORK 14850

1813

DATE MAILED:

08/21/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4-17-95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire Three (3) month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☐ Claims 1-3, 6-22 are pending in the application.
Of the above, claims 6-21 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-3, 22 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1813.

Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 is drawn to a Markush group of chemical compounds, consisting of a) DNAs which encode a specific amino acid sequence, and b) DNAs "that can be used as hybridization probes to isolate a sequence of subparagraph a)". It is not clear which compounds are claimed in subparagraph b), since it is not clear what DNAs are sufficiently specific to be used as probes to isolate a sequence of subparagraph a). To meet the claim limitations, is it sufficient that the DNA cross-hybridize under low stringency, or is it necessary that the DNA be able to hybridize only to a molecule of subparagraph a) in a mixture containing complete mouse genomic DNA? Furthermore, it is not clear what compounds meet the claim limitations, since it is not clear what regions of the sequence are required for the recited use as probes. It is also not clear whether the DNA of part b) consists of or comprises nucleotides that can be used as hybridization probes.

Claims 1-3 and 22 are rejected under 35 U.S.C. § 101 because

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the claimed invention lacks patentable utility. Applicant argues that 4-1BB is known to have biological activity in the immune system, and therefore it inherently has utility. However, the instant specification does not teach a utility in definite and currently available form. Applicant's arguments regarding use in research amount to an argument that the compound can be used in research in order to determine the effect on the immune system of 4-1BB or compounds that interfere with 4-1BB.

In regard to use to make a recombinant protein that can be used to make a monoclonal antibody which can be used to cross-link T cells and enhance T cell activation, there is no evidence on record that a monoclonal antibody having these characteristics can be made reproducibly using expression products of the instant cDNA, nor teachings that the activation is useful for more than a specific class of T cells, nor teachings of how to use the activated T cells.

The specification alleges numerous uses of the claimed cDNA, which are speculations upon possible uses, and proposed avenues of research to determine which of these many possible uses will prove productive. Considering the conflicting suggestions in regard to possible specific biological activities of the 4-1BB product, the specification, taken as a whole, indicates a failure to complete the invention by failing to disclose a current and definitely available utility for the claimed nucleic acid and its

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product.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide a written description and an enabling disclosure.

As discussed in the previous Office action, the specification fails to provide an adequate written description of DNAs useful as probes, since it is not clear what regions of the sequence are adequate for use as a probe as required in claim 22.

In addition, as discussed above under § 101, the specification fails to adequately teach how to use the claimed cDNA, absent undue experimentation.

Claims 1-3 and 22 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-3 and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kwon et al (BO), for reasons of record. Applicant questions how a reference can be enabling to support a rejection when a similar disclosure is not considered enabling

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for purposes of effective filing date. Applicant is claiming a chemical compound, and case law has established that a claim to a compound must be supported by a disclosure of how to use the compound to meet the requirements of 35 USC § 112, first paragraph and 35 USC § 101. However, a reference teaching the same compound does not require teachings of how-to-use to anticipate the invention under 35 USC 102 (In re Schoenwald, 22 USPQ2d 1671).

Applicant's arguments filed April 17, 1995 have been fully considered but they are not deemed to be persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph. D., whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday-Thursday from 6:30 AM-4:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine Nucker, can be

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reached on (703) 308-4028.

The fax phone number for art unit 1813 is (703) 305-7939. Certain papers related to this application may be submitted by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (October 19, 1988) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 19, 1995


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800